K123172

510(k) Summary

DEC 2 1 2012

Manufacturer: Katalyst Surgical, LLC
754 Goddard Avenue
Chesterfield, MO 63005
636-536-5950 (phone)
636-787-0603 (fax)

Contact: Mona Dean
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Date Prepared: **October 5, 2012**

Device Trade Name: Kogent Bipolar Forceps

Common Name: Bipolar Forceps

Classification: 21 CFR 878.4400; Electrosurgical cutting and coagulation device and accessories

Class: II

Product Code: GEI

Indications for Use:
The Kogent Disposable Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation of tissue. The Kogent Disposable Irrigating Bipolar Forceps are a single use product sold sterile and are intended for use in electrosurgery for coagulation and irrigation of tissue.

Device Description:
This device is a disposable bipolar forceps, designed for single use in electrosurgical procedures. They require connection with a suitable bipolar cable to the bipolar output of an electrosurgical generator. These forceps are designed to grasp, manipulate, coagulate, and irrigate, when applicable, selected tissues. The irrigation tube is designed to carry fluid to the tips of the instrument. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator and activated by a footswitch. The devices are provided sterile by ethylene oxide and in sterile packs.

Predicate Device:

The Kogent Bipolar Forceps was shown to be substantially equivalent to the previously cleared devices: Synergetics Disposable Spetzler-Malis Bipolar forceps K121426 and Synergetics Disposable Spetzler Malis Dual Irrigating Bipolar Forceps K110924.

Performance Testing Summary:

The Kogent Bipolar Forceps performance testing is summarized below.

Test Criteria	Description	Lower Spec	Upper Spec	Units	Standard Reference	Result
HF Leakage Current	Leakage current	-	Ileakage=1.8x10^-5 x d x L x ftest xUpeak [mA]	mA	201.8.8.3.102 IEC_60601-2-2_Ed5_2009	**PASS**
HF Dielectric Strength	Active accessory HF dielectric strength	120 % of the rated accessory voltage.		KV	201.8.8.3.103 IEC_60601-2-2_Ed5_2009	**PASS**
Mains Frequency Dielectric Strength	The test duration shall be 30 seconds for active connectors	Pass/ Fail - 3.0KV at 60HZ Frequency		KV	201.8.8.3.104 IEC_60601-2-2_Ed5_2009	**PASS**
Dielectric Withstand	Scan the cord of active accessory for 5 minutes.	Pass/ Fail - 3.0KV at 60HZ Frequency		KV		
Anchorage	Workmanship	Pass/ Fail - Cable fails the test if it separates from the connectors, or termination during any phase of the test		-	201.8.10.4.2 IEC_60601-2-2_Ed5_2009	**PASS**
	Resistance/ Continuity	-	0.2	Ohms		

Substantial Equivalence:
Bench testing demonstrates that the Kogent Bipolar Forceps are substantially equivalent to the Synergetics Disposable Spetzler-Malis Bipolar forceps K121426 and Synergetics Disposable Spetzler Malis Dual Irrigating Bipolar Forceps K110924.

SUMMARY OF EQUIVALENCE

FDA File Reference No.	510(k) No. K110924	510(k) No. 121426
TECHNOLOGICAL CHARACTERISTICS	Comparison Result	Comparison Result
Indications for Use	Identical	Identical
Target Population	Identical	Identical
Design	Similar	Similar
Materials	Similar	Similar
Performance	Identical	Identical
Sterility	Identical	Identical
Biocompatibility	Identical	Identical
Anatomical Sites	Identical	Identical
Human Factors	Identical	Identical
Energy Used and/or Delivered	Identical	Identical
Compatibility with Environment and Other Devices	Similar	Similar
Where Used	Identical	Identical
Electrical Safety	Identical	Identical
Thermal Safety	Identical	Identical
Radiation Safety	Identical	Identical

Conclusion
The Kogent Bipolar Forceps were shown to be substantially equivalent to previously cleared devices with respect to intended use, indications for use, technological characteristics, performance characteristics, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Katalyst Surgical, LLC
% Ms. Mona Dean
Quality and Regulatory Manager
754 Goddard Avenue
Chesterfield, Missouri 63005

December 21, 2012

Re: K123172
Trade/Device Name: Kogent Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 05, 2012
Received: December 06, 2012

Dear Ms. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Pre-enact

Device Name: Kogent Bipolar Forceps

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen
2012.12.20 12:33:10 -05'00'

(Division Sign-off)
Division of Surgical Devices
510(k) Number K123172